

THAT WHICH IS CLAIMED:

1. A method of treating a cancer characterized by overexpression of the HER2 receptor protein in a subject, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and interleukin-2 (IL-2) or variant thereof, wherein said concurrent therapy promotes a positive therapeutic response in a treated subject.
2. The method of claim 1, wherein said positive therapeutic response is greater than a therapeutic response that would be observed with therapy using said anti-HER2 antibody or fragment thereof alone.
3. The method of claim 1, wherein said concurrent therapy comprises administering to said subject at least one therapeutically effective dose of a pharmaceutical composition comprising said IL-2 or variant thereof in combination with a dosing regimen for said anti-HER2 antibody or fragment thereof.
4. The method of claim 3, wherein said IL-2 or variant thereof is administered subcutaneously.
5. The method of claim 3, wherein said anti-HER2 antibody comprises at least one human constant region.
6. The method of claim 3, wherein said anti-HER2 antibody is selected from the group consisting of 4D5 and 520C9, or fragment thereof.
7. The method of claim 3, wherein said pharmaceutical composition comprising IL-2 is selected from the group consisting of a stabilized monomeric IL-2 pharmaceutical composition, a multimeric IL-2 composition, a stabilized lyophilized IL-2 pharmaceutical composition, and a stabilized spray-dried IL-2 pharmaceutical composition.

8. The method of claim 7, wherein said IL-2 is recombinantly produced IL-2 having an amino acid sequence for human IL-2 or variant thereof.

5 9. The method of claim 8, wherein said variant thereof has an amino acid sequence having at least about 70% sequence identity to the amino acid sequence for said human IL-2.

10 10. The method of claim 9, wherein said anti-HER2 antibody comprises at least one human constant region.

11. The method of claim 9, wherein said anti-HER2 antibody is selected from the group consisting of 4D5 and 520C9, or fragment thereof.

15 12. The method of claim 3, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.5 mIU/m² to about 4.0 mIU/m².

20 13. The method of claim 12, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.6 mIU/m² to about 3.0 mIU/m².

25 14. The method of claim 13, wherein said therapeutically effective dose of said anti-HER2 antibody is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.8 mIU/m² to about 1.5 mIU/m².

15. The method of claim 14, wherein said therapeutically effective dose of said anti-HER2 antibody is about 4.0 mg/m² and wherein said therapeutically effective dose of IL-2 or variant thereof is about 1.0 mIU/m².

16. The method of claim 3, wherein said concurrent therapy comprises a first administration of said IL-2 or variant thereof on day 1 of a treatment period followed by a first administration of said anti-HER2 antibody or fragment thereof within 6 days of said first administration of said anti-HER2 antibody or fragment thereof to said subject.

17. The method of claim 3, wherein said concurrent therapy comprises multiple dosing of said anti-HER2 antibody or fragment thereof and said IL-2 or variant thereof.

18. The method of claim 17, wherein said multiple dosing comprises administering said IL-2 or variant thereof and said anti-HER2 antibody or fragment thereof during an introductory cycle, wherein said introductory cycle comprises administering a daily dose of said IL-2 or variant thereof on day 1 of said introductory cycle through day 20 of said introductory cycle, and administering a single dose of said anti-HER2 antibody on day 7 of said introductory cycle.

19. The method of claim 18, further comprising administering said IL-2 or variant thereof and said anti-HER2 antibody or fragment thereof during at least one subsequent cycle, wherein said subsequent cycle comprises administering a daily dose of IL-2 or variant thereof on day 1 of said subsequent cycle through day 14 of said subsequent cycle, and administering said anti-HER2 antibody on day 1 of said subsequent cycle.

20. The method of claim 18, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of a pharmaceutical composition comprising IL-2 or variant

Sub
B2

thereof, wherein said intermediate dose comprises about 12.0 mIU/m² IL-2 or variant thereof.

21. The method of claim 19, further comprising intermediate-dose IL-2

5 pulsing on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of a pharmaceutical composition comprising IL-2 or variant thereof, wherein said intermediate dose comprises about 12.0 mIU/m² IL-2 or variant thereof.

10